
Handbook of PHARMACEUTICAL EXCIPIENTS

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Poloxamer

Nonproprietary Name

F: Poloxamer

Functional Category

SP: Wetting and/or solubilizing agent; emulsifying and/or

solubilizing agent

Others: Nonionic emulsifying, solubilizing, wetting, foaming and gel-forming agent

onyms

luronic F-68, Poloxalkol, Monolan, Supronic

Chemical Names and CAS Registry Number

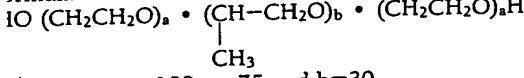
oxirane, methyl-, polymer with oxirane

oxyethylene-propylene glycol

-Hydro- ω -hydroxypoly(oxyethylene)_a poly(oxypropylene)_b (27-31 moles) poly(oxyethylene)_a block copolymer (a=2-130; b=15-67) CAS registry number [9003-11-6]

Empirical Formula and Molecular Weight

Poloxamer 188 is one of a series of poly (oxyethylene), poly (oxypropylene) block polymers with the general empirical formula



For poloxamer 188: a=75 and b=30

Average molecular weight=8350

Structural Formula

See above

Commercial Availability

JSA

BASF Wyandotte Corporation

JK

A.B.M. Chemicals, Ltd.

BASF (UK) Ltd.

Diamond Shamrock U.K., Ltd.

Echinezine Kuhlmann Ltd.

Method of Manufacture

Propylene oxide is condensed onto a propylene glycol nucleus, followed by condensation of ethylene oxide onto both ends of the poly (oxypropylene) base.

Description

White, waxy, free-flowing prilled granules or cast solid; practically tasteless and odorless.

Pharmacopeial Specifications

Test	NF
pH (1 in 40 solution)	5.0-7.5
Arsenic	≤ 3 ppm
Heavy metals	$\leq 0.002\%$
Average molecular weight	90.0-110.0% of label (1,000-7,000) 80.0-120.0% of label (above 7,000) 85.0-115.0% of label Within 1 of label
Polyoxypropylene number	
Polyoxyethylene number	

11. Typical Properties

Antimicrobial action: nil; supports mold growth in aqueous solution

Aqueous gelation concentration: between 60 and 90% at room temperature

Cloud point (Aqueous, 1% and 10%): more than 100°C

Flash point: 260°C

HLB value: ~ 29

Interfacial tension: 25°C, 0.1%-19.8 dynes/cm; 0.01%-24.0 dynes/cm; 0.001%-26.0 dynes/cm

Loss on drying: ~ 0.5%

Melting point: 52°C

pH: between 6.0 and 7.4 (2.5% w/v)

Solubility: soluble in water, dilute acids and ethyl alcohol; slightly soluble in toluene and xylene; insoluble in propylene glycol, perchloroethylene, glycerin, mineral oil and liquid paraffin

Specific gravity: ~ 1.06 g/cm³ at 25°C

Surface tension: 25°C, 0.1%-50.3 dynes/cm; 25°C, 0.01%-51.2 dynes/cm; 25°C, 0.001%-53.6 dynes/cm

Viscosity: 1000 cps at 77°C as a melt (Brookfield)

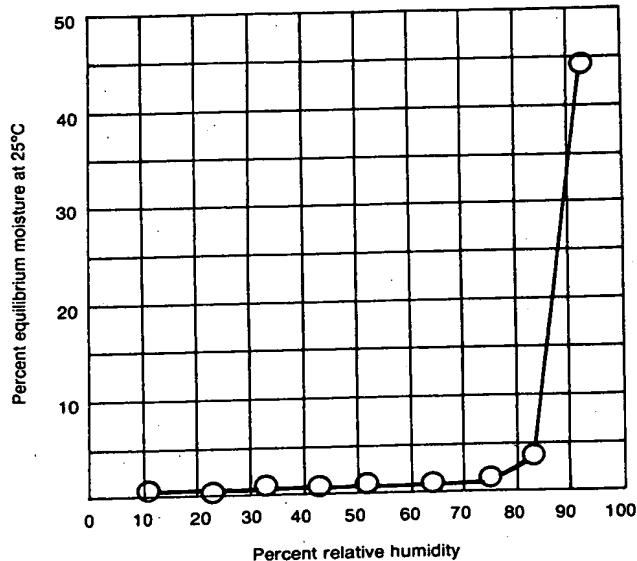
Hygroscopicity: very slight

Flowability: free flowing

Academy HPE Laboratory Project Data
Poloxamer 188 (Pluronic F-68)

Test	Method	Lab #	Results (mg/cm ³)
Solubility (Water 25°C)	SOL-7	32	500
(Water 37°C)			500
(Alcohol 25°C)			398
(Alcohol 37°C)			396
(Prop. Glycol 25°C)			1.0
(Prop. Glycol 37°C)			1.0
(Hexane 25°C)			0.05
(Hexane 37°C)			0.09
Moisture content	MC-3	32	0.33%
EMC Plot	EMC-1	15	Fig:15-EMC-5

Supplier: BASF Wyandotte Corp.



Poloxamer 188, Pluronic F-68 (BASF, Lot #WPEA535B)

Figure: 15-EMC-5 Method: EMC-1

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